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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,600	STEINDLER ET AL.	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of January 30, 2006, to the non-final action dated November 7, 2005 has been entered. Claims 30-39 were amended by the Applicant and remain pending in the application.

Upon further reconsideration of the totality of the prior art, it is the examiner's position that the previous rejection of claims 30-39 under 35 U.S.C. 112 first paragraph (scope of enablement), and claims 37-39 under 35 U.S.C. 101 (non-statutory subject matter), were made in error, as the issues regarding the stem cells of the instant application were not addressed correctly. Therefore a new ground for rejection will be made as follows (*infra*). In view of said reconsideration, the scope of enablement rejection and the non-statutory rejection, set forth in the office action of November 7, 2005 are withdrawn and prosecution of claims 30-39 continued. This action is therefore non-final.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33-37 depend from claim 30 and recite the limitation "wherein the pluripotent brain stem cell" in the second line of the claims. There is insufficient antecedent basis for this limitation in the claim. Claim 30 recites multipotent progenitor or precursor brain stem cells.

Claim 37 is further indefinite. The claim is drawn to the isolated brain stem cells of claim 30, wherein the pluripotent stem cell has been introduced into a tissue in an animal subject. The claim is indefinite because said brain stem cells may not at once be isolated and be present in an

animal subject. As such, the brain cells would no longer remain isolated. Claim 38 depends from claim 37 and claim 39 depends from claim 38.

Response to Arguments - 35 USC § 101

Claims 37-39 were rejected under 35 USC § 101 in the first office action dated November 7, 2005. Applicant's Arguments of January 30, 2006 are moot, as the rejections of claims 37-39 under 35 U.S.C. 101 have been withdrawn, and further in view of the rejections under 35 U.S.C. 112, second paragraph. (*Supra*).

Claim Rejections - 35 USC § 112, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 30 is directed to an isolated culture of multipotent progenitor or precursor brain stem cells containing a sub-population of cells that are immunonegative for glial fibrillary protein, nestin and TuJ1, wherein said culture is capable of differentiation into Type II and Type III clones, that positively display markers for glial fibrillary acidic protein, nestin and TuJ1. Claims 31-39 depend from claim 30 and are directed to isolated brain stem cells.

The specification describes the dissociation of brain tissue and subsequent propagation of the cells in suspension cultures and concludes: "some type II cells are also present in these cultures" (Example 1, last paragraph). The specification further discloses: "The different types of clones observed in the cultures described above and in the experiments described below, represent a continuum of cell proliferation and differentiation" (lines 7-8, p. 12). Examples 1, 2

and 3 of the specification further teach that the continuum of cell differentiation, is dependent in part on the cell culture conditions. The specification does not describe either the isolation or the purification of a subpopulation of cells that may be described as either Type I or Type II and are immunonegative for the markers tested. Moreover, it is apparent from the preceding that the culture of brain stem cells contains both Type I and Type II clones. As such, the Artisan of skill could not predict that Applicant possessed an isolated sub-population of brain cells or isolated brain cells. Hence, only a culture containing a mixed population of brain progenitor or precursor stem cells from mouse and human could be demonstrated as possessed.

The claims additionally encompass an enormous number of multipotent brain stem cells from numerous species of animals, including a substantial number mammalian species (claim 33) and murine species (claim 35). As such, the claims encompass a tremendous number of multipotent brain stem cells that may be isolated, and thus constitute a claimed genus that encompasses other stem cells yet to be discovered.

The specification describes methods that can be used to isolate, amplify and grow a mixed population of stem/precursor cells from the brains of mouse and adult human (Examples I-III). However, the specification provides no cross-species analysis to demonstrate that such cells may be derived from an enormous number of animal species or a substantial number of mammalian species or murine species, that include rat or gerbil. Moreover, Applicant's specification provides no examples of additional species for sources of Type I, II and III clones, to provide an adequate representation for a multitude of animal species. The disclosure to the instant application states that Type I clones are immunonegative for all of the cell-specific cell markers tested so far (lines 24-25, p. 7). Further stating that Type II clones are also immunonegative for cell-specific markers for approximately ten days to two weeks *in vitro* (lines 16-22, p. 8). Therefore, there are no identified markers associated with these cells following their isolation, that can confirm their identification in numerous species. Moreover, the specification further states: "The different types of clones observed in the cultures described above and in the experiments described below, represent a continuum of cell proliferation and differentiation, with the existence of both early and late type II clones...that eventually differentiate into type III clusters...The potential for numerous, undefined hematopoeitic stem cells still exists...The use of just one feature as an identification tool can occur, although it makes the recognition of the

specific stem cell type rather tenuous" (lines 7-17, p. 12). Moreover, Figure 7 shows that the type II adult mouse sphere is approximately 100 microns in diameter, while the type II adult human sphere is approximately 200 microns in diameter. Therefore, the morphological differences observed between mouse and human cell spheres, taken with the lack of any specific markers of type I and II clones following their isolation, further confirms that any extrapolation of the current findings to other animal or mammalian species would be premature and that possession of said cells could be demonstrated only for mouse and human.

As such, the Artisan of skill could not predict that Applicant possessed any additional species, except for mouse and human. Hence, only cells or clones from mouse and human could be demonstrated as possessed.

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that the Artisan can reasonably conclude that the inventor(s) had possession of the claimed invention. Such possession may be demonstrated by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and/or formulae that fully set forth the claimed invention. Possession may be shown by an actual reduction to practice, showing that the invention was "ready for patenting", or by describing distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention (January 5, 2001 Fed. Reg., Vol. 66, No. 4, pp. 1099-11). MPEP §2163.

Applicant's attention is directed to *In re Shokal*, 113 USPQ 283 (CCPA 1957), wherein it is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 CCPA (Patents) 1309, 97 F2d 623, 38 USPQ 189; *In re Wahlforss*, 28 CCPA (Patents) 867, 117 F2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of an isolated sub-population of multipotent

progenitor or precursor brain stem cells, or an enormous number of multipotent brain stem cell from numerous species of animals, including mammalian and murine species, at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

Response to Claim Rejections - 35 USC § 112, Written Description

Claims 33 and 35 were rejected under 35 USC § 112, first paragraph, in the first office action dated November 7, 2005. Applicant's Arguments of January 30, 2006 have been fully considered but not found to be persuasive. Applicant argues that the stem cells have been described in detail, providing morphological and phenotypic descriptions. Applicant further argues that the identified markers that characterize these cells are the hallmarks of these cells and can be identified in any species that bears the counterpart marker of these cells. Applicant further argues that the morphological and phenotypic data can be combined with these markers to identify these cells in different animals, and referring to the descriptions of the phenotypic and morphological data in Figures 17, pages 5, 6, 7 and 12 of the specification.

The disclosure to the instant application states that Type I clones are immunonegative for all of the cell-specific cell markers tested so far (lines 24-25, p. 7). Further stating that Type II clones are also immunonegative for cell-specific markers for approximately ten days to two weeks *in vitro* (lines 16-22, p. 8). Therefore, there are no identified markers associated with these cells following their isolation, that can confirm their identification in any species, as argued by Applicants. Moreover, the specification further states: "The different types of clones observed in the cultures described above and in the experiments described below, represent a continuum of cell proliferation and differentiation, with the existence of both early and late type II clones...that eventually differentiate into type III clusters...The potential for numerous, undefined hematopoeitic stem cells still exists...The use of just one feature as an identification tool can occur, although it makes the recognition of the specific stem cell type rather tenuous" (lines 7-17, p. 12).

Regarding the phenotypic or morphological data, Figure 7 shows (as also indicated in Applicant's arguments), that the type II adult mouse sphere is approximately 100 microns in diameter, while the type II adult human sphere is approximately 200 microns in diameter.

Therefore, applicant's own admission in the morphological differences observed between mouse and human cell spheres, taken with the admitted lack of any specific markers of type I and II clones following their initial culture, further confirms that any extrapolation of the current findings to other mammalian species would be premature and that possession of said cells could be demonstrated only for mouse and human.

Hence, the rejection is maintained for reasons of record and expanded upon by the commentary given above (Supra).

Claim Rejections - 35 USC § 112-Lack of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for an isolated culture of multipotent, progenitor or precursor brain stem cells that are immunonegative for glial fibrillary protein, nestin and TuJ1, wherein said culture is capable of differentiation into Type II and Type III clones, that positively display markers for glial fibrillary acidic protein, nestin and TuJ1, as claimed.

In determining whether Applicant's claims are enabled, it must be found that one of skill in the art at the time of invention by Applicant would not have had to perform "undue experimentation" to make and/or use the invention claimed. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404:

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance

presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

MPEP § 2164.04 states: "[W]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection."

The Nature Of The Invention And Breadth Of Claims

Claims 30-32 are drawn to an isolated culture of, multipotent progenitor or precursor brain stem cells containing a sub-population of cells that are immunonegative for glial fibrillary acidic protein, nestin and TuJ1 markers, wherein said culture is capable of differentiation into Type II and Type III clones, that positively display marker for glial fibrillary acidic protein, nestin and Tuj1. Claim 33 further limits the brain stem cells to mammalian cells. Claims 34 and 35 narrow the mammalian brain stem cells to human and murine respectively. Claim 36 is directed to isolated brain stem cells "obtained from" a post-mortem animal subject. Claims 37-39 are directed to isolated brain stem cells that have been introduced into a tissue of an animal subject. Because these claims encompass a wide range of conditions and phenotypes (including phenotypes defined by negative limitations), associated with a number of different differentiated cell types, under several biological conditions, the detail of the disclosure provided by Applicant, in view of the prior art, must encompass a wide knowledge, so that one of skill in the art, at the time of invention by Applicant (hereafter the "Artisan"), would be able to practice the invention as claimed by Applicant, without undue burden being imposed on such Artisan. This burden has not been met because it would require undue experimentation to produce an isolated culture of multipotent progenitor or precursor brain stem cells containing a sub-population of cells that are immunonegative for glial fibrillary acidic protein, nestin and TuJ1, that are further capable of differentiation into Type II and Type III clones, that positively display marker for glial fibrillary acidic protein, nestin and Tuj1 as claimed in the instant application.

The Unpredictability Of The Art And The State Of The Prior Art

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The state of the prior art is effectively summarized by the references of Weiss et al. (U.S. Patent No. 5,851,832; filed Jun. 7, 1995); Boss et al.(U.S. Patent No. 5,411,883; filed Aug. 12, 1992); Johe (U.S. Patent No. 5,753,506; filed Aug. 12, 1992); Gage et al. (Ann. Rev. Neurosci. 18:159-192; 1995); Reynolds et al. (Dev. Biol. 175:1-13; 1996) and Laywell et al. (Neurosci. Abs. 232:297, 1997).

The art teaches the feasibility for the isolation and propagation of multipotent neural stem cells that under certain culture conditions may undergo subsequent differentiation into glia, astrocytes and neurons (Weiss, Example 20, second paragraph). However, the art also teaches that the resulting differentiated phenotypes and morphological properties resulting from a population of multipotent neural stem cells is dependent upon isolation and culturing conditions and is highly unpredictable (Gage et al., pp. 174-175). Further, at the time of the invention, the art teaches methods for obtaining a population of cells that may be enriched in multipotent neural stem cells (Weiss, columns 10 and 11), but does not teach an isolated culture of progenitor cells containing a sub-population of brain stem cells that are immunonegative for glial fibrillary acidic protein, nestin and TuJ1, that are further capable of differentiation into Type II and Type III clones, that positively display marker for glial fibrillary acidic protein, nestin and TuJ1.

The instant claims are drawn to a broad phenotype of a sub-population of cells that do not positively display any stated surface markers and are further capable of differentiation into Type II and Type III clones, that is not apparent from the disclosure of the invention. In view of the lack of teachings or guidance provided by the specification with regard to an enabled, isolated multipotent sub-population of brain stem cells, the lack of teachings or guidance provided by the specification to overcome the art-recognized unpredictability and difficulty inherent in isolation of purified stem cells, and the lack of correlation between the multipotent immunonegative sub-population of cells of the present invention and Type II and Type III clones as claimed, and for the specific reasons cited above, it would have required undue experimentation for an Artisan of skill to make and use the claimed invention. Hence, absent a strong showing by Applicant, in the

way of specific guidance and direction, and/or working examples demonstrating the same, such invention as claimed by Applicant is not enabled.

The Amount Of Direction Or Guidance Presented And Working Examples

The specification fails to disclose adequate representations of an isolated sub-population of brain stem cells that are immunonegative for glial fibrillary acidic protein, nestin and TuJ1, and are further capable of differentiation into Type II and Type III clones. The specification provides for the culture of a mixed population of cells that include Type I cells obtained from mouse and human brain tissue following dissociation. The specification outlines the culture conditions and concludes: "some type II cells are also present in these cultures" (Example 1, last paragraph). The specification states: "type I clones exhibit areas of very small, punctuate staining interspersed with regions that lack staining...and cells of individual clones are not separable by trypsinization. Furthermore, type I clones are immunonegative for all of the cell-specific markers tested so far." (lines 21-25, p. 7 and Figure 1B). The specification discloses: "The different types of clones observed in the cultures described above and in the experiments described below, represent a continuum of cell proliferation and differentiation" (lines 7-8, p. 12).

The specification states: Immediately after they appear in culture, type II clones are immunonegative for cell-specific markers" (lines 16-17, p. 8). The production of type II clones and the relevant culture conditions are disclosed in Example 2. The type II culture clones are described as containing dense debris for 10-14 days and further, that some type III clones were present. Example 5 teaches that EM analysis of type II clones revealed rings of small, tightly apposed cells that often surround a core of flocculent, non-cellular material having many of the characteristics of extracellular matrix (second paragraph). Example 3 teaches conditions for the differentiation of type III clones neurons or glia, but not any additional cell types.

Examples 1, 2 and 3 of the specification further teach that there is a continuum of cell differentiation, which in part is dependent on the cell culture conditions. Moreover, it is apparent from the preceding that the culture of brain stem cells contains both Type I and Type II clones. No data or evidence is presented to show that Type I clones or stem cells that are immunonegative for glial fibrillary acidic protein, nestin and TuJ1, are capable of differentiation into Type II and Type III clones. This is further complicated by the observation that upon initial

culture, Type II clones are themselves immunonegative for glial fibrillary acidic protein, nestin and TuJ1. Therefore, a sub-population of multipotent progenitor or precursor stem cells giving rise to immunopositive Type II clones may in fact be immunonegative Type II clones and not Type I clones. Moreover, as the culture contains a mixed population of cells, it would not be possible to determine whether the cells giving rise to or differentiating into Type II and Type III cells are in fact Type I cells, or different stem cells present in the mixed culture or stem cells that are only viable in the brain tissue. Therefore, there is no nexus between Type I cells (clones) and Type II and Type III clones.

A definitive test to show the multipotency of Type I clones, would require their purification from the mixed culture, and subsequent differentiation into Type II and Type III clones. In the absence of any known positively displayed cell surface markers, the purification of Type I clones would require additional experimentation, without any guarantee of success.

The guidance provided by the specification amounts to an invitation for the skilled Artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses a subset of culture conditions for a mixed population of multipotent brain-derived neuronal stem cells.

Quantity Of Experimentation

The quantity of experimentation in this area is extremely large, as there are a significant number of parameters, which would have to be studied and tested to make and definitively show that one is in possession of an isolated sub-population of immunonegative brain stem cells that are capable of differentiation into Type II and Type III clones. This would require a significant degree of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level Of Skill In The Art

The level of skill in the art at the time of invention is deemed to be high. However, because of the immaturity of the art, and its unpredictability, as shown by the other factors, one of skill in the art at the time of invention by Applicant would not have been able to make and/or use the invention claimed without undue experimentation.

Analysis And Conclusion

The guidance provided by the specification amounts to an invitation for the skilled Artisan to try and follow the disclosed instructions to make and use the claimed invention. The detail of the disclosure provided by Applicant, in view of the prior art, must encompass a wide knowledge, so that the Artisan of skill would be able to practice the invention as claimed by Applicant, without undue burden being imposed on such Artisan. In the instant case, and for the specific reasons cited above, in a highly unpredictable art where the correlation between Type I clones and their differentiation into Type II and Type III clones in a mixed culture of different cell types remains unproven, together with the large quantity of research required to define these unpredictable variables, including the lack of any cell surface markers for either Type I or early Type II clones, and the lack of guidance provided in the specification, it is the position of the examiner that it would require undue experimentation for an Artisan of skill to make and use the claimed invention. Hence, absent a strong showing by Applicant, in the way of specific guidance and direction, and/or working examples demonstrating the same, such invention as claimed by Applicant is not enabled.

Response to Claim Rejections - 35 USC § 102

Claims 30-39 were rejected under 35 USC § 102, in the office action of November 7, 2005. Applicant argues that "None of the references cited by the examiner teach the markers that identify each of these isolated stem cells, the methods of isolating them or differentiate them into Type I, II or III type clones". But that the claims have been amended to overcome the Examiner's rejections.

The prior art rejections of claims 30-39 are withdrawn, in view of applicant's arguments, and in view of the lack of enablement regarding the claims of the instant invention.

Conclusion

No claims allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst William Phillips, whose telephone number is **(571) 272-0548**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER